

Does the treatment of anxiety in children with ADHD improve outcomes?

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| Submission date 10/09/2015 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| | | <input checked="" type="checkbox"/> Protocol |
| Registration date 29/09/2015 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 10/06/2020 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Attention deficit hyperactivity disorder (ADHD) is a common disorder that affects behaviour. ADHD can present in a number of ways, but common symptoms include a short attention span, restlessness, hyperactivity and impulsiveness. It has been found that up to half of children with a diagnosis of ADHD also have problems with anxiety. The exact reason for this is unknown, but it may be because the symptoms of ADHD are very disruptive to daily life and can make life a lot more stressful. As well as affecting the children's quality of life, it has been found that their parents are more likely to suffer from mental health difficulties, such as anxiety and depression. There is a lot of evidence to suggest that anxiety problems in children with ADHD may be underreported, as the symptoms of anxiety can be very similar to the ADHD symptoms. This can mean that many children are not treated, and their anxiety problems can get even worse. There are many ways to treat anxiety; however behavioural treatments such as cognitive behavioural therapy (CBT) may be preferable to medication for the children's parents. The aim of this study is to find out how effective a CBT programme, designed to help children to cope better with their anxiety, is for children suffering from ADHD.

Who can participate?

Children aged 8 to 12 years with a diagnosis of ADHD, who show signs of anxiety.

What does the study involve?

Participants are randomly allocated into the treatment group, or the usual care group. Those in the treatment group attend 10 sessions with a clinician to learn strategies to help them to manage their feelings of anxiety. Those in the usual care group receive access to usual care for their ADHD, but no extra help with their feelings of anxiety. After five months, the parents and teachers complete questionnaires about the children's feelings of anxiety and behaviour. The wellbeing and behaviour of the parents are also assessed using questionnaires at this timepoint.

What are the possible benefits and risks of participating?

Benefits of participating may include an improvement in anxiety, which could lead to improvements in the child's behaviour and wellbeing. There are no risks of participating in the study.

Where is the study run from?

Murdoch Childrens Research Institute (Australia)

When is the study starting and how long is it expected to run for?

September 2015 to December 2019

Who is funding the study?

1. Murdoch Childrens Research Institute (Australia)
2. Sidney Myer Fund and Myer Foundation (Australia)
3. The National Health and Medical Research Council (Australia)

Who is the main contact?

Dr Emma Sciberras

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Does the treatment of anxiety in children with ADHD improve outcomes? A large-scale randomised controlled trial

Study objectives

Cognitive behavioural therapy is superior to standard care for the treatment of anxiety in children with ADHD.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Royal Children's Hospital Human Research Ethics Committee, 09/09/2015, ref: 35164

Study design

Single-centre randomised controlled trial of a cognitive behavioural treatment versus usual care

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

1. Attention deficit hyperactivity disorder (ADHD)
2. Anxiety

Interventions

Children in the intervention arm will receive 10 sessions of cognitive behavioural therapy delivered by study trained psychologists, while the control group will continue to access usual care for management of their ADHD.

Intervention Type

Behavioural

Primary outcome(s)

Parent report of whether the child meets criteria for an anxiety disorder (separation anxiety disorder, social phobia, or generalised anxiety disorder) 5 months post-randomisation measured by the Anxiety Disorders Interview Schedule for Children 5.

Key secondary outcome(s)

Secondary outcome measures as of 05/10/2016:

1. Anxiety: Parent and child report of child anxiety symptoms as measured by the Spence Child Anxiety Scale and the Child Anxiety Life Interference Scale; teacher report of anxiety symptoms as measured by the School Anxiety Scale (all measured at baseline, 5 and 12 months post randomisation). Parent report of whether the child meets criteria for an anxiety disorder (separation anxiety disorder, social phobia, or generalised anxiety disorder) 12 months post-randomisation measured by the Anxiety Disorders Interview Schedule for Children 5
2. ADHD symptoms as measured by the ADHD Rating Scale IV (parent and teacher report measured at baseline, 5 and 12 months post randomisation)
2. Psychosocial quality of life as measured by the CHU-9D (parent and child report measured at baseline, 5 and 12 months post randomisation)
3. Behaviour as measured by the Strengths and Difficulties Questionnaire (parent and teacher report measured at baseline, 5 and 12 months post randomisation)
4. Executive functioning as measured by the NIH cognitive toolbox (blinded, direct assessment at baseline, 5 and 12 months post randomisation)
5. Parent mental health as measured by the K6 (measured at baseline, 5 and 12 months post randomisation)
6. Parenting behaviours as measured by a series a questions from the Longitudinal Study of Australian Children (measured at baseline, 5 and 12 months post randomisation)

Original secondary outcome measures:

1. Anxiety: Parent and child report of child anxiety symptoms as measured by the Spence Child Anxiety Scale and the Child Anxiety Life Interference Scale; teacher report of anxiety symptoms as measured by the School Anxiety Scale (all measured at baseline and 5 months post randomisation).
2. ADHD symptoms as measured by the ADHD Rating Scale IV (parent and teacher report measured at baseline and 5 months post randomisation)
2. Psychosocial quality of life as measured by the PedsQL 4.0 (parent and child report measured at baseline and 5 months post randomisation)
3. Behaviour as measured by the Strengths and Difficulties Questionnaire (parent and teacher report measured at baseline and 5 months post randomisation)
4. Executive functioning as measured by the NIH cognitive toolbox (blinded, direct assessment at 5 months post randomisation)
5. Parent mental health as measured by the K6 (measured at baseline and 5 months post randomisation)
6. Parenting behaviours as measured by a series of questions from the Longitudinal Study of Australian Children (measured at baseline and 5 months post randomisation)

Completion date

31/12/2019

Eligibility

Key inclusion criteria

1. Children aged 8 - 12 years
2. Caregiver report of ADHD symptoms meeting Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) criteria for ADHD (child also needs to have been previously diagnosed with ADHD by a paediatrician)
3. Caregiver report of anxiety symptoms meeting Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) criteria for Separation Anxiety Disorder, Generalised Anxiety Disorder, or Social Phobia

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

8 years

Upper age limit

12 years

Sex

All

Key exclusion criteria

1. Receiving specialised treatment for anxiety from a psychologist or psychiatrist. Participants who are taking medication for anxiety can participate provided they are still experiencing significant anxiety symptoms and have been on stable medication for a minimum of six weeks.
2. Major illness or disability.
3. Non-English speaking

Added 05/10/2016:

4. A score of 15 or greater on the Social Communication Questionnaire, a measure of autism symptoms

Date of first enrolment

06/10/2015

Date of final enrolment

31/12/2018

Locations

Countries of recruitment

Australia

Study participating centre

Murdoch Childrens Research Institute (MCRI)

The Royal Children's Hospital
Flemington Rd
Parkville
Australia
3052

Sponsor information

Organisation

Murdoch Childrens Research Institute (MCRI)

ROR

<https://ror.org/048fyec77>

Funder(s)

Funder type

Research organisation

Funder Name

Murdoch Childrens Research Institute

Funder Name

Sidney Myer Fund and Myer Foundation

Alternative Name(s)

Sidney Myer Fund & The Myer Foundation, Sidney Myer Fund and the Myer Foundation, Myer Foundation and Sidney Myer Fund, Myer Foundation & Sidney Myer Fund's

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Australia

Funder Name

The National Health and Medical Research Council

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from emma.sciberras@deakin.edu.au

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| Protocol article | protocol | 13/11/2019 | 10/06/2020 | Yes | No |